II. REMARKS

A. Status of the Claims

Claims 1, 3, 5, 7, 8, 10-20 and 36-56 are pending. Claims 2, 4, 6 and 21-35 were previously cancelled. Claims 45-51 have been cancelled.

B. Rejections under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 44-46 and 48-51 under 35 U.S.C. § 112, first paragraph. The Examiner stated that there is no support in the specification for "hydrocodone bitartrate" in claim 44; "oxycodone hydrochloride" in claim 45; "codeine phosphate" in claim 46; "levorphanol tartrate" in claim 48; "meperidine hydrochloride" in claim 49; "methadone hydrochloride" in claim 50; and "morphine sulfate" in claim 51.

In response, the Examiner is directed to page 7, line 23 for support for "hydrocodone bitartrate". Claims 45-46, and 48-51 have been cancelled.

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be removed.

C. Rejections under 35 U.S.C. § 103

1. Kreek in view of the Dr. Medzon reference

Claims 1, 3, 5, 8, 12-14, 16-20, 44-47, 49-52 and 54-56 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Kreek US 4,769,372 (hereinafter "the Kreek reference"), in view of Dr. Medzon (Clinical Toxicology Review) (hereinafter "the Medzon reference").

This rejection is traversed. Applicants respectfully submit that the Kreek reference teaches away from the use of naltrexone. The Kreek reference utilizes opioid antagonists which are specifically "devoid of systemic antagonist activity when administered orally." (See Kreek abstract). In contrast, naltrexone has systemic antagonist activity when administered orally. The Examiner is respectfully reminded that

" ... [a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away fro the claimed invention." See MPEP 8th Ed., 2nd Rev. § 2141.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983). When viewed in its entirety, one skilled in the art would recognize that the Kreek reference, by specifically stating that the opioid antagonists used are devoid of systemic antagonist activity when administered orally, teaches away from the use of an orally bioavailable opioid antagonist (e.g., naltrexone).

The Examiner is relying on the Medzon reference for allegedly teaching "the use of naltrexone ... in place of naloxone". However, the Medzon reference is directed toward the use of opioid antagonists to provide a systemic effect (i.e. opioid detoxification) and does not teach or suggest that naltrexone can be used in place of naloxone when the intent is to utilize an opioid antagonist devoid of systemic antagonist activity (as utilized in the Kreek reference).

Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over the Kreek reference in view of the Medzon reference be removed.

2. Kreek in view of the Dr. Medzon reference and Mitch et al.

Claims 7, 10, 11, 15, 48 and 53 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Kreek US 4,769,372, in view of Dr. Medzon (Clinical Toxicology Review) and Mitch et al. US 5,998,434 (hereinafter "the Mitch reference").

This rejection is traversed. For the reasons set forth above, Applicants respectfully submit that the Kreek reference and the Medzon reference do not suggest the present invention. Applicants further submit that the Mitch reference does not cure the deficiencies of the Kreek and Medzon references as discussed above.

Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over the Kreek reference in view of the Medzon reference and the Mitch reference be removed.

3. Kreek in view of the Dr. Medzon reference and the FDA consumer reference

Claims 10 and 36-43 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Kreek US 4,769,372, in view of Dr. Medzon (Clinical Toxicology Review) and FDA consumer."

This rejection is traversed. For the reasons set forth above, Applicants respectfully submit that the Kreek reference and the Medzon reference do not suggest the present invention. Applicants further submit that the FDA consumer reference does not cure the deficiencies of the Kreek and Medzon references as discussed above.

Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over the Kreek reference in view of the Medzon reference and the FDA consumer reference be removed.

III. CONCLUSION

It is now believed that the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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